IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

MARIA DALBOTTEN, Plaintiff, v. C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	Case No. 1:20-cv-00034-SPW **ORDER ON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

Before the Court is Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion for Summary Judgment. (Doc. 113). Defendants move for summary judgment on Plaintiff's claims in the Amended Complaint, asserting a fatal lack of causation evidence. (Doc. 118 at 10).[1] Additionally, Defendants move for summary judgment on each of the claims individually. Plaintiff opposes summary judgment on each portion of the motion except Claim IX. (Doc. 147).

I. Background

This case is one of many filed in a multi-district litigation quagmire relating to complications experienced by patients with implanted G2 IVC filters. This specific motion is one of several dozen before the Court—as such the Court will

[1] For consistency, when citing to the docket, the Court will use the page numbers generated by CM/EFC rather than those assigned by the parties themselves.

only provide a brief overview here and incorporate specific facts as necessary. Plaintiff Maria Dalbotten brought this products liability action after experiencing medical complications that she claims were caused by defects in the G2 IVC filter. The filter, put into place to reduce the risk of pulmonary embolism, apparently migrated, pierced the wall of her inferior vena cava, and fractured, leaving a fragment embedded in her heart. Defendants assert that all of Plaintiff's claims fail for lack of causation evidence, arguing that Plaintiff cannot prove that any alleged design, manufacturing, or warning defects caused or contributed to her injuries. (Doc. 118 at 11).

II. Legal Standard

Summary judgment is proper when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). An issue is "genuine" only if there is a sufficient evidentiary basis on which a reasonable fact finder could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is "material" only if it could affect the outcome of the suit under the governing law. *Id.*

In considering a motion for summary judgment, the Court "may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing*

Prods., 530 U.S. 130, 150 (2000); *Anderson,* 477 U.S. at 249-50. The Court must view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in the non-moving party's favor. *Anderson,* 477 U.S. at 255; *Betz v. Trainer Wortham & Co., Inc.,* 504 F.3d 1017, 1020-21 (9th Cir. 2007).

III. Discussion

Defendants move for summary judgment on the entirety of Plaintiff's claims as well as on the separate claims for detailed reasons. The Court will first address the global argument, followed by the specific arguments.

A. Causation

Defendants assert that they are entitled to complete summary judgment because Plaintiff has not provided reliable expert testimony establishing that her injuries were caused by a specific defect in the filter. (Doc. 118 at 13). Defendants agree that Plaintiff suffered an injury when her filter fractured with strut embolization but contend that the possibility of such complications is inherent to all IVC filters and, accordingly, Plaintiff can neither identify a specific defect in her G2 Filter or that a specific defect caused her complications and resulting damages. (Doc. 118 at 14).

Plaintiff responds that Defendants' causation argument fails for four reasons: (1) it misstates the applicable law; (2) Plaintiff's experts can establish a causal link; (3) Defendants adopt the medical causation standard of proof rather than the

products liability standard; and (4) Defendants ignore Plaintiff's failure to warn claims, which use a different causation standard, rendering total summary judgment inapplicable even if Defendants succeed on their other causation arguments. (Doc. 147 at 12).

Plaintiff's contention that she is not required to prove causation at all is overbroad. However, the Court agrees that her experts have tendered evidence supporting a causal link between the alleged defect and Plaintiff's injuries sufficient to survive summary judgment.

For a products liability claim under Montana law, a plaintiff must prove that the product was in a defective condition, unreasonably dangerous to the user, that the defect caused the injury, and that the defect is traceable to the defendant. *Brown v. North Am. Mfg. Co.*, 576 P.2d 711, 718 (Mont. 1978) (citing Restatement (Second) of Torts § 402A); *see also* Mont. Code Ann. § 27-1-719. Causation is ordinarily a question of fact for the trier of fact, although it may be determined as a matter of law where reasonable minds can reach only one conclusion regarding causation. *Riley v. Am. Honda Motor Co.*, 856 P.2d 196, 198 (Mont. 1993). Even given this standard, summary judgment has been granted on similar arguments in sister cases to this one, for failure to tie the specific design defect alleged to the fracturing and migration of the shattered filter. *See Nelson v. C.R. Bard, Inc.*, 2021 WL 3578874, at *12 (S.D. Miss. 2021).

Plaintiff has presented testimony from Dr. McMeeking asserting that the filter was defectively designed and accordingly was likely to tilt, shatter, and migrate to other regions of the heart. (Doc. 148 at 27, ¶ 46). Plaintiff additionally tenders the expert opinion of Dr. Muehrcke, who states that Plaintiff's filter "failed by tilting, perforating, fracturing and embolizing one fragment to her right ventricle and two fractured fragments remained locally. The fragment which migrated to her heart perforated her right ventricle, cause a life-threatening pericardial effusion and long-term pain; until it was removed eight years later." (Doc. 149-5 at 13). Muehrcke also opines that Plaintiff's medical record "fails to indicate any external or internal forces which could have caused her Bard filter to fail." *Id.* He continues:

> the implantation appeared to be appropriately oriented and positioned in the IVC; it was properly deployed. The infrarenal IVC was of appropriate size: measuring 2.1 cm at the time of implantation by Dr. Craig. There were no clots in the IVC. There were no other non-filter related reasons for the IVC filter to caudally migrate, tilt, perforate the IVC and fracture. Ms. Dalbotten's G2 filter failed in a very dangerous manner. It migrated caudally, tilted, perforated the IVC in several points, and interacted with surrounding organs; it fractured and broke off three pieces.

Id. at 14.

Although Defendant insists otherwise, this testimony, viewed in the light most favorable to the Plaintiff, could allow a reasonable jury to conclude that it is more likely than not that defects in the filter specifically caused Plaintiff's injuries. *Cf. Albright v. C.R. Bard Inc.*, 2021 WL 4459725, at *6 (E.D. Wis. 2021) (holding

that the experts could not provide a "causal link" for the alleged injuries). Here, McMeeking has provided evidence suggesting that the filter suffered from a design defect. Muehrcke states that the shattered filter caused Plaintiff's injuries and that there were no alternative causes aside from a defect for the failure of Plaintiff's filter. Whether a defect existed is a fact issue, as is whether the alleged specific design defects caused the failure in this instance. Because Plaintiff has created a genuine dispute of fact, the accuracy and reliability of the evidence adduced by Plaintiff's experts is for the jury to decide, and the matter is inappropriate for summary disposition as to causation.

B. Independent Arguments

Defendants assert that each of Plaintiff's claims should be summarily dismissed for independent reasons. (Doc. 118 at 16-17). The Court will address each in the order presented by Defendants.

1. Failure to Warn (Count III)

Defendants assert that they are entitled to summary judgment on Plaintiff's strict liability failure to warn claim because Bard's warnings were accurate, Plaintiff cannot establish that an insufficient warning caused her injuries, and Defendant has no duty to warn of comparative rates of complication. (Doc. 118 at 19). Defendants argue that the undisputed evidence demonstrates that the warnings provided to the learned intermediary—in this case Dr. Craig, the

implanting physician—were adequate because they warned of the precise alleged injury-causing risks: fracture, migration, perforation, and embolization. Defendants state that they had no duty to warn if these risks were higher or more likely to occur in the G2 filter than other similar filters.

"To establish that a particular product is defective and unreasonably dangerous, a plaintiff must prove that it is capable of causing injury to the user beyond that which would be expected by the ordinary user. *Winters v. Country Home Prods.*, 654 F. Supp. 2d 1173, 1180 (D. Mont. 2009). A product may be defective in the way that it is designed or manufactured, or if the warnings accompanying the product are inadequate. *Wood v. Old Trapper Taxi*, 925 P.2d 1375, 1379-82 (Mont. 1997). Under the learned intermediary doctrine, a medical or pharmaceutical manufacturer's duty to warn runs to the prescribing and treating physicians, rather than necessarily to the patients themselves. *Stevens v. Novartis Pharms. Corp.*, 247 P.3d 244, 257 (Mont. 2010). However, the rationale underpinning the doctrine of a singular doctor-patient relationship has changed as the modern healthcare system has decentralized; now patients receive an increasing majority of their care from nurses, nurse practitioners, physicians' assistants, and doctors other than the prescribing physician. *Id.* at 257-58. As such, the learned intermediary doctrine has evolved to include these providers, as well as patients themselves, depending on the unique facts of the treatment scenario. *Id.* This

evolution renders the doctrine less strict and more of a case-by-case guideline. Accordingly, Defendants here may have a broader duty to warn the class of care providers (and even Plaintiff) than solely the prescribing physician.

Here, the instructions for use ("IFUs") for the G2 filter contained the following:

Warnings

- **Filter fractures is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any serious adverse clinical sequelae.**
- **Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.**

(Doc. 148 at 35-36, ¶ 58 (emphasis original)). And:

Potential Complications

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fractures is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any serious adverse clinical sequelae.
- Perforation or other acute chronic damage of the IVC wall.

- **All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.**

(Doc. 148 at 36, ¶ 36 (emphasis original)).

According to Defendants, this warning (which the Court notes is for all IVC filters and does not specifically refer to the G2 filter) adequately and clearly warns of the potential risks and complications. Defendant further asserts that Plaintiff cannot establish a causal link between any alleged deficiencies in the warnings provided and the prescribing physician's decision to select or use the G2 filter. Defendants cite to the deposition testimony of Dr. Craig, the implanting physician, who stated that he was aware of the risks of perforation, migration, fracture, and embolization inherent in IVC filters and that he would not "make a different decision, even having been made aware of a subsequent poor outcome." (Doc. 118 at 26 (citing Doc. 117 at 32-33, ¶ 81)).

Plaintiff disputes this reading of Craig's deposition testimony and notes that the "different decision" he references can be fairly read to mean that he would have prescribed an IVC filter either way, but not necessarily the G2. Plaintiff buttresses this argument by noting that later in his deposition, Craig stated that he would have wanted to know if the G2 experienced higher rates of migration and fracture and

that the IFU did not indicate the degree of potential harm posed by this increased risk, rendering the warnings provided both inadequate and a proximate cause of Plaintiff's injuries. (Doc. 147 at 25).

As previously stated, the non-moving party (Plaintiff, in this instance) is entitled to all favorable inferences when determining if there is a genuine dispute of material fact on a given issue. Considering the evidence in the light most favorable to the Plaintiff, the Court concludes that issues of disputed fact regarding both the adequacy of the warnings provided and whether Craig would have acted differently if provided more information about the degree and severity of G2 filter complications and failure preclude summary judgment. Craig's testimony is sufficiently ambiguous and can be interpreted several ways, each with legal significance. This creates a fact issue that the jury must decide.

Montana strict product liability caselaw does not require a warning to differentiate between comparative rates of complication. Defendants request that the Court interpret this gap in the law as evidence that such warnings are not required. (*See* Doc. 118 at 30-31). The Court declines to adopt such a rule. On a similar issue of first impression, applying Georgia law, the Ninth Circuit noted both the pros and cons of requiring comparative rate warnings, including the difficulties placed on manufacturers weighed against the need for physicians to have complete information and their expertise at evaluating data. *In re Bard IVC*

Filters Product Liability Litigation, 969 F.3d 1067, 1076-77 (9th Cir. 2020). The Ninth Circuit ultimately concluded in the absence of a categorical prohibition against such a claim that the jury may decide the adequacy of the warning. *Id.* The Court agrees with this reasoning and that conclusion is bolstered by Craig's deposition statements that he would have wanted to know and counsel his patients regarding comparative failure rates. As such, the Court will not grant summary judgment on this claim.

2. Strict Liability Design Defect (Count II)

Defendants assert that Plaintiff's strict liability design defect claim fails as a matter of law because it is barred by Comment k to § 402A of the Restatement (Second) of Torts, and because Plaintiff has not produced evidence that the G2 filter was defective and unreasonably dangerous, or that the defect was the proximate cause of her injuries. (Doc. 118 at 31). Comment k to § 402A reads:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. [...] Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate

> consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Montana has adopted § 402 of the Restatement (Second) of Torts. *See Brown*, 576 P.2d at 718. Montana courts have not yet applied Comment k to medical devices. Defendants urge the Court to adopt and employ it here to bar Plaintiff's claim. The Court declines to do so for two reasons. First, it is unclear whether the Montana Supreme Court would endorse such adoption. The Court has been silent on the matter and the Montana Products Liability Act does not have language suggesting that the legislature intended to prohibit a class of claims. *See, e.g.,* Mont. Code Ann. §27-1-719. Second, whether a product, specifically IVC filters, are "quite incapable of being made safe" is a factual question to be left to the jury. The reasonability of the risks balanced against the utility of the product is unsuitable for summary disposition.

Defendants next argue that, regardless of Comment k's application, Plaintiff has not met her burden to show that a fact issue exists regarding whether the G2 filter was defective and unreasonably dangerous, and to proximately link any defect to her injuries. (Doc. 118 at 34). A product is defective if it is unreasonably unsuitable for its intended or foreseeable purpose. *Neether v. Coleman Co.*, 2005 U.S. Dist. LEXIS 47711, at *19-20. (D. Mont. 2005). The defect alleged must cause the injuries complained of and be traceable to the defendant; it also must be

capable of causing injury beyond what the ordinary user would expect. *Winters*, 654 F. Supp. 2d at 1180.

In support of her design defect claim, Plaintiff relies again on McMeeking's testimony that the G2 filter was designed in a manner that could not withstand expected forces within the heart, was likely to shatter due to the sharp corners built into the filter, and migrate and tilt due to the dimensions of the filter arms. (Doc. 148 at 27, ¶ 46). McMeeking also plans to testify that several alternative designs could have reduced or eliminated these risks. (Doc. 148 at 27, ¶ 46). This proposed evidence is sufficient to create a fact issue as to whether the G2 filter was unreasonably unsuitable for its intended purpose. As stated previously, the Court has determined that Plaintiff has proven a genuine issue of material fact as to the cause of her injuries. *See* Section III.A, *supra*. Accordingly, the Court denies summary judgment on Plaintiff's design defect claim.

3. Manufacturing Defect (Count I)

Defendants move for summary judgment on Plaintiff's strict liability manufacturing defect claim, arguing that Plaintiff has not produced any expert testimony to support her claim that a manufacturing defect existed in the G2 filter. (Doc. 118 at 37). Defendants contend that Plaintiff has not presented any evidence that the specific filter implanted in Plaintiff deviated from Bard's underlying

design or manufacturing specifications for the G2 filter or that any defects caused her injuries.

Expert testimony is necessary when the issue presented is beyond the common experience of the trier of fact and the testimony will assist the trier of fact in determining the issue or understanding the evidence. *Johnson v. Am. Honda Motor Co.*, 923 F. Supp. 2d 1269, 1279 (D. Mont. 2013). Obviously medical device manufacturing is far beyond the experience of a layperson, so Plaintiff must provide sufficient expert evidence. In support, Plaintiff provides Dr. Ritchie's opinions regarding how the G2 filter did not conform to Bard's intended design specifications because a sampling of the filters had unintended gouges, draw markings, and surface damage that he believes were caused by the shape-setting process during manufacture. (Doc. 148 at 28-29, ¶ 49). Though Ritchie did not examine Plaintiff's explanted filter, he did examine failed G2 filters of other patients and two sample unused G2 filters. (Doc. 149-6 at 14). He determined that the sample filters showed pock-marked and scratched surfaces consistent with the failures demonstrated by the removed filters that he examined. (Doc. 149-6 at 17-19). He found that these errors were inconsistent with the prototype G2 designs he examined.

Ritchie's opinions regarding the manufacturing issues present in the sample filters are sufficient to defend against summary judgment at this time. Other

questions, such as the relevance of the examination of other failed G2 filters, may be appropriately addressed at a later stage, but, for the purpose of the current analysis, viewing the evidence in the light most favorable to Plaintiff, Ritchie's opinion creates sufficient dispute over whether the G2 filter suffered from a manufacturing defect rendering summary disposition inappropriate.

4. Breach of Warranty (Counts IV, V, and VI)

Defendants argue that Plaintiff's breach of warranty claims fail because she did not provide pre-suit notice in accordance with Montana law. (Doc. 118 at 38). Montana Code Annotated § 30-2-607(3)(a) requires a party suing for breach of warranty to "within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Courts have construed this provision to require pre-suit notice of intent to bring warranty claims. *See Potter v. Ethicon, Inc.*, 2021 WL 6498267, at *3 (D. Mont 2021). Plaintiff responds that the pre-suit notice requirement was satisfied by her filing the short form complaint in the governing multi-district litigation case. (Doc. 147 at 31). Plaintiff analogizes to *Stevens*, where the Montana Supreme Court held that an earlier-filed class action complaint tolled the statute of limitations because it provided notice to the defendant in the mass tort litigation of the general intent to sue. 247 P.3d at 252.

The Court finds that this analogy is insufficient to overcome the clear language and intent of the pre-suit notice requirement for warranty claims codified in Montana Code Annotated § 30-2-607(3)(a). Class action issues and equitable tolling of a statute of limitations are not analogous to the straightforward and unambiguous notice required for warranty claims under Montana law. Because it is undisputed that Plaintiff did not provide pre-suit notice of intent to make breach of warranty claims, summary judgment on these counts is appropriate.

5. Fraudulent Concealment and Constructive Fraud Claims (Counts VII and VIII).

Defendants assert that Plaintiff's fraud claims must fail because Plaintiff has not produced any evidence that Bard intended to deceive or shown reliance by Craig or Plaintiff on any allegedly fraudulent statements. (Doc. 118 at 42). A prima facie claim of constructive fraud requires the following elements: (1) a representation; (2) the falsity of that representation; (3) the materiality of that representation; (4) the speaker's knowledge of that representation's falsity or ignorance of its truth; (5) the hearer's ignorance of that representation's falsity; (6) the hearer's reliance upon the truth of that representation; (7) the hearer's right to rely upon that representation; and (8) the hearer's consequent and proximate injury or damage caused by reliance on that representation. *Dewey v. Stringer*, 325 P.3d 1236, 1240 (Mont. 2014).

Defendants assert that Plaintiff has not demonstrated reliance or causation. (Doc. 118 at 42-43). They argue that Craig did not rely on Bard's representations and in support cite to Craig's deposition testimony that he relied more on his experience and medical training than the IFU or information from Bard sales representatives, such as brochures. *Id.* Plaintiff responds that she has produced evidence that Bard made affirmative untrue and inaccurate statements about the G2 filter's migration resistance and improvements over previous iterations, as well as evidence that Bard withheld relevant safety information from doctors and regulators. (Doc. 143 at 37-39; Doc. 144 at 75-81).

As noted previously, Craig also stated in his deposition that he would have made different treatment decisions had he known of the dramatically increased failure rates of the G2 filter. (Doc. 143 at 40). He further stated that he understood fractures to be extremely rare and believed that no one would expect a fracture to occur. *Id.* Viewing this evidence in the light most favorable to the Plaintiff, as required, this statement can be fairly interpreted as Craig stating that he relied on Bard's statements that the G2 filter carried the same risks and failure rates as previous iterations. Put another way, had he been provided accurate information about the G2 filter's drawbacks, he would have acted differently. A jury could reasonably conclude that this evidence is sufficient to meet the reliance and causation elements of fraudulent concealment and constructive fraud.

Accordingly, Plaintiff has produced evidence creating a genuine issue of material fact as to falsity and reliance. Therefore, summary judgment is inappropriate on these counts.

6. Intentional and Malicious Acts and Omissions (Count IX)

Plaintiff concedes that these allegations do not constitution a cognizable independent claim under Montana law and, accordingly, summary judgment is appropriate. As such, Count IX is dismissed, although Plaintiff may rely on the allegations in support of Count IX to support of her other claims, such as her fraud claims.

IV. Conclusion

Defendants' Motion for Summary Judgment is GRANTED on Counts IV, V, VI, and IX and DENIED as to all other claims.

DATED this 11th day of January, 2023.

Susan P. Watters

SUSAN P. WATTERS
United States District Judge